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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,704	07/18/2001	Mark H. Vickers	3911-7	2234

7590 09/03/2004

SHELDON R. MYERS  
FLIESLER DUBB MEYER AND LOVEJOY, LLP  
FOUR EMBARCADERO CENTER  
FOURTH FLOOR  
SAN FRANCISCO, CA 94111-4156

EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/856,704

### Applicant(s)

VICKERS ET AL.

### Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 20-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. This office action is in response to the remarks filed on 5/11/2004. Claims 1-12 and 20-28 are pending.
2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph, maintained***

3. Applicant's remarks of 5/11/2004 have been fully considered. The remarks with respect to the animal model, intrauterine under nutrition/growth retardation and the choosing the correct dose is found to be persuasive and the Office will withdraw the lack of enablement provision with respect to these issues. However, Applicant's remarks with respect to the effect of adverse postnatal environment are deemed to be not persuasive. Therefore, the rejection of claims 1-12 and 20-28 under 35 USC § 112 1<sup>st</sup> paragraph lacking of enablement is maintained with respect to the scope of an adverse post natal environment is maintained.

The instant specification fails to describe how adverse postnatal environments will affect hypertension. For example, a divorced family or lead paint in the house or 2<sup>nd</sup> hand smoke can all be considered as adverse postnatal environments. However, the specification fails to establish the nexus between any adverse postnatal environment and hypertension. It is generally accepted that hypertension in humans is a multifactorial disease with the involvement of diet, genetic make up and other factors such as environment being involved. However, there is no direction provided by the inventor with respect to what if any contribution these postnatal environmental factors or

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any other adverse post-natal environment will have on hypertension in an individual.

Although, Applicant contends that body mass index (BMI) can be used to diagnose adverse post-natal environment (see page 8 of remarks), there is no guidance provided for this determination. Therefore, given the breadth of claims 1 and 2, in light of the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention for treating hypertension in mammals as recited. Thus, the rejection of claims 1-12 and 20-28 under 35 USC § 112 1<sup>st</sup> paragraph for scope of enablement is maintained.

***Claim Rejections - 35 USC § 102, maintained***

4. Claims 1, 2, 4-6, 8, 11 and 12 remain rejected under 35 USC § 102(b) as being anticipated by Johannsson et al. (1997) for reasons set forth in the Office Action of 9/30/2003, page: 7. Applicant's arguments filed on 5/11/2004 have been considered but are not persuasive.

Applicant asserts that Johannsson et al., discloses the use of growth hormone to diastolic blood pressure in obese men, but does not demonstrate any effect on systolic blood pressure. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., systolic blood pressure) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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Further, Applicant asserts that patients in Johannsson et al. are not hypertensive. However, the reference in page 728, 2<sup>nd</sup> paragraph it clearly teaches that " In the rhGH-treated group, two patients were receiving treatment for hypertension with atenolol and nifedipine." Therefore, the Office contends that the patient population studied in the reference included hypertensive patients. Further, upon treatment with rhGH, they indicate that there is a decrease in (diastolic) blood pressure (page 730, 2<sup>nd</sup> column), again meeting the instant claim limitation. Further, Applicant's arguments with respect to lack of correlation between changes in diastolic and systolic blood pressure in Johannsson et al. reference is noted. However, as indicated above these limitations are not recited in the claims. Claims are drawn to using GH to reduce blood pressure. The Office also notes the teachings of Izzo et al. reference. Again, in response to applicant's argument that the Johannsson et al. reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., systolic blood pressure) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, claims 1, 2, 4-6, 8, 11 and 12 remain rejected under 35 USC § 102(b) as being anticipated by Johannsson et al.

5. No claims are allowable.

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**6. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

#### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

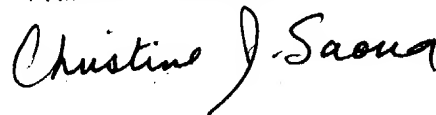
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 08/04

CHRISTINE J. SAOUD  
PRIMARY EXAMINER

A handwritten signature in black ink that reads "Christine J. Saoud". The signature is written in a cursive style with a large, stylized "J" and "S".